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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543

27752 7590 01/13/2003

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EXAMINER

DECLoux, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



**Advisory Action**

Application No.

09/607,602

Applicant(s)

DOYLE ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 2-4 and 7.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Continuation of 5. does NOT place the application in condition for allowance because: Continuation of 5. does NOT place the application in condition for allowance because: the outstanding 102 rejections have been maintained. Applicant traverse the rejections on the grounds that the present claims define a new method for a "new use", ie promoting whole body health by topical administration to the oral cavity of a composition comprising an antimicrobial agent optionally with a H2 antagonist, and as such is distinguishable from Bristol-Myers Squibb v Ben Venue Laboratories 58 USPQ 2d 1508 (CAFC 246 F.3d 1368 2001). Applicants contend that the present purpose of promoting whole body health is distinguishable over Bristol because the purpose is not disclosed in the prior art as in Bristol, and Applicant is not attempting to claim newly discovered results of a known process directed to the same purpose as in Bristol, but rather Applicant is claiming a "novel and unobvious process by virtue of a new use or a different purpose". It is noted by the examiner that the instant claims recite an identical process of administering an identical composition as that taught in the referenced art, and further that the court recognized in *In re Woodruff* 16USPQ2d 1934 1936 that it is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 632-33, 2 USPQ2d 1051, 1054 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987); *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375, 197 USPQ 134, 139 (5th Cir. 1978). With respect to Applicant's case, it is the examiner's position that Applicant has discovered a new benefit (whole body health) of an old process (topical administration to the oral cavity of an antimicrobial agent optionally with an H2 antagonist). Applicant refers to the declaration by Robert Singer stating that H2 antagonists enhance the function of key mechanisms of the gingival barrier function, and that from these findings applicant contends that it is evident that the topical application of H2 antagonists to oral tissues represents a unique and unanticipated approach to increasing the barrier function of periodontal tissues. However, the Examiner contends that these findings are the discovery of a new benefit of an old process based on inherent benefits resulting from said old process.

Applicant also traverses the inherency aspect of said rejection, because there is no disclosure in the prior art that a method involving topical administration, as opposed to systemic administration, of a composition comprising H2 antagonist compounds would be useful in promoting systemic health. However, it is noted that the instant claims do not recite the systemic administration of said composition.

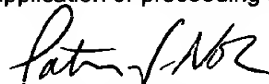
Applicant further traverses the rejection by contending that a second medicinal use of a substance already known to be useful in treating a disease is patentable, and cites several examples of such patents. However, it is noted by the examiner, that in all of Applicant's cited examples of said patents, the patient population which are subject to the methods of the patented first and second medicinal uses of a substance, differs. In applicant's case, the claimed methods are applied to the same population as the referenced methods. Therefore, though Applicant's arguments have been fully considered, they are not deemed persuasive, and the rejections are maintained essentially for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
January 9, 2003



Patrick J. Nolan, Ph.D.  
Primary Patent Examiner,  
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